EPA comments to the Draft Baseline Human Health Risk Assessment Work Plan
Columbia Falls Aluminum Company NPL Site
Columbia Falls, Montana

Responses Prepared for Columbia Falls Aluminum Company, LLC by Roux / EHS Support, LLC
Dated February 13, 2018

General Comments – USEPA Comments in Black. Roux / EHS Support LLC responses in blue. USEPA Response to Roux / EHS Support LLC responses are in green. Responses are only included when further discussion or follow-up may be needed. Roux / EHS Support LLC responses in orange.

1) A formal background evaluation is required to substantiate any conclusions drawn regarding risks from chemicals not being Site-related. Ideally, this would be presented using multiple lines of evidence (statistical comparison of regional background data to Site data, statistical comparison of Site-specific background data to Site data, graphical presentations, and evaluation of risks based on background concentrations).

A background investigation will be conducted as part of the Phase II site Investigation. A Background Investigation Sampling and Analysis Plan (Background SAP) will be prepared to provide details on the investigation and how it will be incorporated into the Baseline Human Health Risk Assessment (BHHRA).

Specific Comments - USEPA Comments in Black. Roux / EHS Support LLC responses in blue.

Section 1.0 (Page 1) – Please add "Superfund" when first mentioning the Site name.

The BHHRA Work Plan (WP) will be revised as requested.

1) Section 1.1 (Page 1) – Site Boundary –Modify this section to use the terminology "Study Area" until the extent of contamination has been determined. In Figure 1, the orange line in the legend description should also be revised to "Study Area".

The Site and the site boundary are defined in the Administrative Settlement Agreement and Order on Consent (AOC) and Remedial Investigation and Feasibility Study (RI/FS) Work Plan; and, it is proposed to keep referring to them as per the prior reports submitted to date. It is acknowledged that the United States Environmental Protection Agency (USEPA) may modify the Site boundary in the future, if warranted.

2) Section 2.3 (Page 6) – Revise the following statement to include the potential of future land owners accessing groundwater, "*There is not current or planned use of groundwater as a potable source at the Site. In addition, based upon the depth to groundwater and current and future Site use, there is no potential for direct exposure of humans (i.e., construction workers) to groundwater at the Site*". While it may be true that water is not to be used as a potable water source at this time, this statement does not reflect potential future use if the property were to be sold in the future. Because of this, potential risk due to groundwater exposure needs to be evaluated in the HHRA.

As discussed at the meeting, Columbia Falls Aluminum Company (CFAC) has no intention of allowing the contaminated groundwater at the Site to be used for potable purposes and, as property owner, can ensure that this does not happen in the future. However, it is understood that EPA and Montana Department of Environmental Quality (MDEQ) feel that an evaluation of risks associated with the potential future use of groundwater must be included as part of the Baseline Human Health Risk Assessment (BHHRA). Therefore, the BHHRA WP will be revised to include an evaluation of groundwater as a drinking water source.

3) Section 2.4.1 (Page 8) – Further evaluation is needed to support conclusions regarding cyanide presence/absence. As stated, *"Cyanide has not been detected in any of the wells during any of the ten sampling events completed by USEPA and/or CFAC since the cyanide was detected in the 2013 sampling, indicating that cyanide is not present in the groundwater beneath Aluminum City."* Cyanide has been detected in samples above the U.S. Environmental Protection Agency (USEPA) tapwater Regional Screening Level (RSL) (0.15 micrograms per liter [µg/L]) at levels of 111 µg/L and 18 µg/L. The adequacy of the detection limits for other sampling events must be evaluated relative to the tapwater RSL before conclusions can be drawn with confidence. Provide additional information on the cyanide detection limits achieved relative to screening levels with the statement referenced.

The text of the BHHRA WP will be revised as follows: "*Cyanide has not been detected in any of the wells during any of the ten sampling events completed by USEPA and/or CFAC since the cyanide was detected in the 2013 sampling. The cyanide MDL for the sampling has varied between 5 ug/L and 10 ug/L; in comparison the tap water RSL for cyanide is 0.15 ug/L and the MCL is 200 ug/L. The sampling results indicate that cyanide is not present in the groundwater beneath Aluminum City at concentrations at or above the detection limit.*"

During the laboratory selection process, Roux Associates evaluated the proposed method detection limits (MDL) against the desired limits based on the screening criteria, and TestAmerica was able to meet more of the desired detection limits than each of the other laboratories evaluated. In the cases where the laboratory could not meet the desired detection limit, such as cyanide at 0.15 ug/l, it is because the screening level is extremely low (i.e., less than the detection limit of most laboratories).

EPA Response: The comment has not been addressed regarding detection limit adequacy relative to risk evaluation. Will the adequacy of the detection limits for other sampling events be evaluated relative to the tapwater RSL before conclusions can be drawn with confidence? A statement regarding this evaluation should be included.

Roux/EHS Response: The text of the BHHRA WP will be revised as follows: *"Cyanide has not been detected in any of the wells during any of the ten sampling events completed by USEPA and/or CFAC since the cyanide was detected in the 2013 sampling. The MDLs reported for cyanide (5 ug/l and 10 ug/l) represent the lowest MDLs achievable by the laboratory analyzing the groundwater samples from Aluminum City residential wells. It is recognized that these MDLs exceed the USEPA Tapwater RSLs. The sampling results indicate that cyanide is not present in the groundwater beneath Aluminum City at concentrations at or above the detection limit. The adequacy of cyanide MDLs achieved during future sampling events will be continue to be evaluated relative to Tapwater RSLs, and where MDLs exceed such screening criteria, it will be noted and discussed as appropriate in the uncertainty sections of the risk assessment reports."*

4) Section 2.4.1 (Page 8) – Further evaluation in the HHRA is needed to support conclusions regarding fluoride concentrations in Aluminum City and their comparability to background. Provide additional information on the fluoride concentrations observed in background samples, the number of background samples available for consideration, and a statistical comparison of the two datasets (site vs. background).

The background data set consists of 117 public water supply (PWS) wells that reported fluoride concentrations to MDEQ from 2013 to 2016. MDEQ has indicated in their e-mail correspondence on February 5, 2018, that "None of the public water systems in Flathead County are adding fluoride to their water supplies so all of the detected amounts are naturally occurring fluoride. As you can see in the results we have one area in Flathead County where naturally occurring fluoride is greater than 1.0 mg/L, and that is west of Kalispell in the Smith Valley/Kila area." A two-sample t-test was performed to compare the means of groundwater fluoride concentrations collected from PWS wells in Flathead County to groundwater fluoride concentrations measured in Aluminum City wells, utilizing ProUCL (version 5.0). When performing the comparison, the background wells exhibiting elevated concentrations of fluoride (i.e., greater than 1.0 mg/L) were treated as outliers and excluded from the dataset. The results of the comparison indicate that mean concentration beneath Aluminum City is less than the mean concentration in Flathead County PWS wells. The text of HHRA WP will be revised to incorporate this discussion and analysis; the data and ProUCL output will be included in an Appendix to the BHHRA WP.

EPA Response: The identification of outliers appears to be arbitrary, a formal outlier test should be performed. It is unclear how a cutoff of 1.0 mg/L determined and how many outliers were removed. This information should be included. It is also suggested that a scatter plot of the data be added to demonstrate the variability and identify the outliers.

Roux/EHS Response: The above referenced statistical analysis, including a formal outlier test, was performed for the PWS and Aluminum City datasets. A full description of the analysis, including the data, outlier tests performed and outliers removed, graphs generated, and ProUCL outputs is provided as Appendix A to this response. The results of the analysis indicate the mean fluoride concentration beneath Aluminum City is less than the mean concentration in Flathead County PWS wells. The text of HHRA WP will be revised to reference and summarize the statistical analysis; the Appendix A attached to this response will be included as an Appendix to the BHHRA WP.

5) Section 2.4.2 (Page 8) – The evaluation of soil vapor is limited in that it only considers concentrations of VOCs in groundwater. Expand the soil vapor evaluation to include an assessment of soil gas data using the VISL calculator, in addition to the groundwater data. Global comment – modify all statements that occur later in the document to include information on soil gas and groundwater.

As part of the Phase I Site Characterization, Amplified Geochemical Imaging (AGI) passive soil gas sampling devices were deployed to assess for the potential presence of volatile organic compounds (VOCs) and certain areas of the Site. The results from the passive samplers are reported in mass adsorbed on the sampling device, not as a concentration. Therefore, it is not possible to use the Vapor Intrusion Screening Level (VISL) calculator as requested by the above comment. The results of the passive soil gas survey were presented in the Phase I SAP Addendum (Roux Associates, 2016), and used to justify the addition and modification of soil boring and/or monitoring well locations to target areas where VOCs were detected. Note that there were no VOCs detected in soil at

concentrations exceeding a Residential RSL in any of the 132 shallow or 135 intermediate-depth samples analyzed for VOCs as part of the Phase I Site Characterization. In addition, VOCs were typically non-detect in groundwater across the Site. As described in the BHHRA WP, for the VOCs that were detected, the maximum concentrations were used in the VISL calculator to assess the potential risk associated with soil vapor pathway. The results indicated carcinogenic risks were less than 1x 10-6 and that hazard quotient (HQ) for all VOCs detected were less than 0.1.

6) Section 2.4.3 (Page 9) – Expand the conclusion that "*there is no potential for exposure to asbestos by human receptor activity in the Asbestos Landfills*" to state under what conditions this is true. Because only surficial soils were sampled, characterization of subsurface soils is lacking. If subsurface soils are disturbed, there is potential for asbestos exposure. In addition, it needs to be noted that asbestos-containing building material have a tendency to rise from the subsurface and become exposed.

The BHHRA WP will be revised to expand on the conclusion as requested.

7) Section 2.4.2 (Page 9). Please include a citation for the toxicity equivalency factors that were used in the evaluation. Please expand this evaluation to include a table of the comparisons to RSLs. This applies to all three bullets where conclusions are drawn based on a comparison that is not presented.

The BHHRA WP will be revised to reference the Phase I report and tables; a reference for the toxicity equivalency factors (TEFs) used in the evaluation will be provided.

8) Section 2.5 (Page 10) – It is inappropriate to consider mitigation factors at this stage in the CERCLA process. In accordance with USEPA risk assessment guidance for Superfund (USEPA 1989), the baseline HHRA "*...is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action).*" The risk assessment should present risks to receptors at the Site under current and future conditions if no actions were taken to limit potential exposures; it is not appropriate to evaluate future conditions if mitigation were to occur. Please remove mention and application of mitigation factors.

References to mitigation factors, such as institutional controls, land covers (except for existing landfill covers) and groundwater use restrictions that may be implemented for future risk management will be removed from the BHHRA WP. As noted in the response to Comment 3, the BHHRA WP will be revised to indicate that the baseline risk assessment will include an evaluation of groundwater as a drinking water source.

9) Section 2.5 (Page 10) – The workplan would benefit from having a figure/flow diagram depicting the conceptual site model.

The Work Plan will be revised to include a figure that presents the potentially complete exposure pathways including media, receptor, and exposure route presented in the Conceptual Site Model (CSM).

10) 2.5.2 (Page 11) – The workplan does not address how will ingestion of game will be evaluated at the Site. Because animals will not restrict their use to certain exposure units where recreational receptors may hunt, consideration of the mobility of game animals is needed. Granted there may not

be designated recreational use in an exposure unit, the game animals will be exposed to multiple exposure units (EUs) (i.e., those that are accessible to animals). Text describing the approach for evaluating game tissue ingestion needs to be added.

The exposure assumptions and intake models/equations for the game and fish ingestion exposure scenarios will be included in the Table 4 series for the BHHRA as interim deliverables; the interim deliverable will include a cover memo describing the overall approach and details on the methodology; and, the BHHRA WP will be revised to note the submittal of these tables as interim deliverables.

11) 2.5.3.11 (Page 18) – The HHRA should evaluate exposures due to groundwater ingestion for the most conservative receptor in each EU at a minimum under a hypothetical future use scenario to demonstrate if groundwater could be used for consumption in the future.

As noted in the response to Comment 3, the BHHRA WP will be revised to indicate that the baseline risk assessment will include an evaluation of groundwater as a drinking water source.

12) 3.1.1.1 (Page 20) – Provide clarification regarding the use of samples collected using discrete and incremental sampling methodology (ISM). The workplan must explain how exposure point concentrations (EPCs) will be calculated in each of the EUs given the differences in sample collection techniques.

The EPCs will be calculated separately for discrete versus ISM samples for each EU for inclusion in the Table 3 series based on the final database for the BHHRA (i.e., inclusive of Phase II Site Investigation results). For the interim deliverable, a cover memo describing the overall approach and details on the methodology for calculation of the EPCs for the applicable exposure scenarios will be submitted with example calculations for one COPC per exposure area scenario. The complete Table 3 series will be submitted with the BHHRA report. The Work Plan will be revised to note the submittal of the cover memo and example tables as interim deliverables.

13) 3.1.1.2 (Page 20) – The workplan must provide a discussion of data quality, beyond completeness and rejected data. This discussion should include information on sample representativeness, method comparability, result accuracy and precision, sample variability, and analytic sensitivity.

The BHHRA WP will be revised to provide this discussion.

14) 3.1.1 (Page 20) – Please add a discussion of the representativeness of the data for each EU and media type. This discussion must determine if available data are representative of the range of temporal and spatial variability at the Site and whether every EU have been adequately characterized. In particular, in cases where only discrete soil samples are available for an EU or when only one ISM replicate is available for an EU, the workplan must discuss whether the available data are adequate to support a risk characterization of soil.

A discussion of the representativeness of the data for each EU and media type will be added.

15) Section 3.1.1.3 (Page 21) – Please provide a citation for the USEPA RSL version that was used in the chemical of potential concern (COPC) selection.

The BHHRA Work Plan will be revised to include the citation for the USEPA RSLs used in the selection of COPCs.

16) Section 3.1.1.3 (Page 21) – Please provide an explanation for how COPCs will be selected for media types other than soil, sediment, and surface water (e.g., game tissue, fish tissue, and air).

The BHHRA WP will be revised to discuss how COPCs will be selected for game and fish tissue; note that there is no selection for COPCs in air for the groundwater volatile vapor exposure pathway because there are no applicable soil gas concentration data; soil vapor and fugitive dust exposure pathway is evaluated using the RSLs that include these pathways in their development.

17) Section 3.1.1.3 (Page 22) – Revise the last bullet. Granted that "*groundwater data indicate[ing] that leaching of the COPC in the soil is not affecting the groundwater quality*", it must be demonstrated in the risk assessment rather than cited in another source.

The bullet in Section 3.1.1.3 will be replaced with a section that identifies and discusses COPCs detected at concentrations exceeding the USEPA risk based soil screening levels (RBSSL) for soil leaching to groundwater and the additional screening step conducted for these COPCs. The following italicized text will be incorporated into this section to justify the additional screening step for COPCs; which primarily address VOCs and semi-volatile organic compounds (SVOCs). It is also noted that the written e-mail correspondence comments from the MDEQ Project Manager on January 15, 2018, indicate agreement with the finding that VOCs and SVOCs are not an issue in groundwater at the Site, and that these constituents do not warrant further analysis at Site.

If a VOC or SVOC in soil exceeded the USEPA RBSSL for potential to leach to groundwater, but did not exceed the USEPA RSL or MDEQ RBSL for direct contact with soil, and was not a selected as a COPC in Site-wide groundwater, it was not selected as a COPC in soil. This decision is based upon the groundwater data indicating that leaching of the COPC in the soil is not affecting the groundwater quality. The evaluation of VOCs and SVOCs in groundwater included 158 groundwater samples, from 42 monitoring wells, over four quarterly rounds of sampling (including both low and high water conditions). In addition, as specified in the RI/FS Work Plan and the Phase I SAP, the monitoring well locations sampled for VOCs and SVOCs were biased toward potential source areas to determine whether any of these constituents required further evaluation as COPCs. The table below provides summary statistics VOCs and SVOCs detected in groundwater in comparison to screening levels:

Group	*Determimand*	*No. of Results*	*No. of Detections*	*Percent Detections*	*Min Concentration*	*Max Concentration*	*DEQ 7 Standard*	*USEPA MCL*	*USEPA Tapwater RSL*
SVOCs	*3 & 4 Methylphenol*	*158*	*3*	*1.9%*	*<0.88*	*42.0*	*-*	*-*	*-*
	4,6-Dinitro-2-methylphenol	*158*	*1*	*0.6%*	*<2*	*2.2*	*13*	*-*	*-*
	Bis(2-ethylhexyl) phthalate	*158*	*6*	*3.8%*	*<0.72*	*2.4*	*6*	*6*	*5.6*
	Di-n-butyl phthalate	*158*	*3*	*1.9%*	*<0.82*	*1.3*	*2000*	*-*	*-*
VOCs	*1,1,1-Trichloroethane*	*158*	*4*	*2.5%*	*<0.28*	*3.8*	*200*	*200*	*800*

Group	Determinand	No. of Results	No. of Detections	Percent Detections	Min Concentration	Max Concentration	DEQ 7 Standard	USEPA MCL	USEPA Tapwater RSL
	1,1-Dichloroethane	158	4	2.5%	<0.24	0.95	4	-	2.8
	1,2-Dichloroethane	158	1	0.6%	<0.25	0.28	4	5	0.17
	2-Butanone (MEK)	158	1	0.6%	<2.2	2.3	-	-	560
	Acetone	158	13	8.2%	<1.1	13.0			1400
	Benzene	158	4	2.5%	<0.09	0.17	5	5	0.46
	Carbon disulfide	158	2	1.3%	<0.22	3.0	-	-	81
	Dichlorodifluoromethane	158	3	1.9%	<0.14	3.5	1000	-	20
	Methylene Chloride	158	5	3.2%	<0.21	1.8	5	5	11
	Tetrachloroethene	158	15	9.5%	<0.12	0.69	5	5	4.1
	Toluene	158	5	3.2%	<0.25	2.2	1000	1000	110
	Trichloroethene	158	4	2.5%	<0.22	0.76	5	5	0.28

The data indicate the low frequency of detection and the low concentrations of VOCs and SVOCs in groundwater. Based upon these data, no VOCs and SVOCs were retained as COPCs in groundwater. The fact that VOCs and SVOCs are not present in groundwater at levels of concern immediately downgradient of potential sources demonstrates that leaching from the soil into groundwater is not occurring or is negligible. This approach to evaluating groundwater data to determine that leachability is not a concern is also consistent with MDEQ guidance (MDEQ, 2016a).

EPA Response: The comment states that a comparison to screening levels. While it is recognized that summary statistics and the screening values is presented, there isn't a comparison presented. There are multiple exceedances (1,2-Dichloroethane and Trichloroethene) of the USEPA Tapwater RSL that are not identified (highlighted in green). The statement, "*Based upon these data, no VOCs and SVOCs were retained as COPCs in groundwater.*" is not appropriate given the exceedances observed in the table above.

Roux/EHS Response: As stated in Section 3.1.1.3 Selection of COPCs, the frequency of detection was considered when retaining COPCs. For data sets with at least 20 samples, a COPC detected in five percent or fewer of the samples was not retained as a COPC (USEPA, 1989) provided samples with detected concentrations do not indicate the presence of potential hot spots (i.e., high concentrations in a small spatial area). As such, if a COPC in soil exceeded the USEPA RBSSL for potential to leach to groundwater, but did not exceed the USEPA RSL or MDEQ RBSL for direct contact with soil, and the COPC in soil was not a COPC in Site-wide groundwater, it was not selected as a COPC in soil. This decision is based upon the groundwater data indicating that leaching of the COPC in the soil is not affecting the groundwater quality. This approach is consistent with described in Section 5, Example 1, of the MDEQ Risk Based Corrective Action Guidance (MDEQ, 2016a).

Although 1,2-Dichloroethane and Trichloroethene maximum concentrations in groundwater were above their respective USEPA RSLs, these contaminants were detected at a frequency of 2.5% or less, and the maximum concentrations were less than 1 ug/L. Based on the above described COPC selection rationale, and based upon the fact that the maximum concentrations in soil were less than

residential direct exposure criteria, it is Roux's position that these contaminants should not be retained as COPCs in groundwater or soil. It is also noted that MDEQ has stated in its February 7, 2018 comments that the data indicate that VOCs do not appear to be an issue at the Site. As discussed with USEPA in a conference call on March 19, 2018, groundwater samples from all new Phase II monitoring wells will be analyzed for VOCs in both of the 2018 sampling rounds to obtain a full analytical data set for the new well locations and to confirm the current understanding of Site conditions.

18) Section 3.1.1.3 (Page 22) – Revise the workplan to clearly discuss how background data will be used in the risk assessment process. In accordance with USEPA guidance (USEPA 2002a), background data may be used in the risk characterization to determine if risks are attributable to the Site, but chemicals should not be removed during the COPC selection process on the basis of background.

The BHHRA WP presents a preliminary selection of COPCs based on the current Phase I database; there were no COPCs removed from selection based on background. The discussion of background is presented to help inform the development of the Phase II SAP and the Phase II background study. Clarification will be provided for the use of background in the selection of COPCs and risk characterization sections.

19) Section 3.1.1.3 (Page 22) – Revise the workplan to identify the basis of toxicity values, in cases where the selected values are not directly used as presented in the USEPA RSL table. See below for example text that should be included for chromium for additional information:

Chromium: Although measured chromium concentrations in environmental media were based on total chromium, for the purposes of COPC selection, maximum concentrations will be compared to RSLs based on hexavalent chromium [Cr(VI)], which is the more toxic form. The RSL table identifies screening levels for oral exposure to soil or water based on the assumption that Cr(VI) is carcinogenic by the oral route. However, EPA's Integrated Risk Information System (IRIS) database states "No data were located in the available literature that suggested that Cr(VI) is carcinogenic by the oral route of exposure." For this reason, the screening levels for Cr(VI) in soil and water will be set equal to the non-cancer RSLs.

The BHHRA Work Plan will be revised to expand and clarify the basis of toxicity values and their use in the USEPA RSL table versus their use in the selection of COPC process.

20) Section 3.1.1.3.1 (Page 22) – It is recommended the workplan consider the future changes to the lead criterion. The November 2017 version of the USEPA RSL table presents a value of 400 milligrams per kilogram (mg/kg) as the residential lead soil screening value, however, this value is based on a target blood lead level of 10 micrograms per deciliter (µg/dL) and does not reflect recent changes in USEPA guidance on lead modeling (e.g., USEPA 2017a,b). USEPA Region 8 recommends the following when performing lead risk assessments: evaluate risks for a range of target blood lead levels (i.e., 5, 8, and 10 µg/dL), employ modified ingestion rates (von Lindern et al. 2016), revise the child age range to be 12-72 months (USEPA 2017b), revise the maternal blood lead to 0.8 µg/dL (USEPA 2017a), and change the default water concentration to 0.8 µg/L. It is recognized that the current version of the USEPA RSLs (November 2017) do not reflect these changes. However, these changes in approach were recently approved by the USEPA Technical Review Workgroup (TRW) during the lead consultation for another Region 8 Superfund site (Eagle Mine). Evaluation of risks due to lead will be

revisited at the time of the 5-year review for the Site; however, inclusion of these changes now may limit potential future re-work as part of the 5-year review. This is a global comment to be considered for all receptors.

As discussed at the meeting and shown on Figure 1 attached to these response to comments, the Phase I results indicate lead is not an important COPC at the Site. Soil samples will continue to be analyzed for lead during the Phase II Site Characterization. The BHHRA WP will be revised to note that the lead screening level used for the preliminary screening is being considered for revision, and that final screening of COPCs after completion of the Phase II Site Characterization will use EPA RSLs and MDEQ guidance that are in effect at that time.

EPA Response: There are areas of the Site that have not been adequately characterized at this time. It is premature to draw the conclusions that lead is not an important COPC at the Site.

Roux/EHS Response: The EPA response is noted and the Work Plan will not state that lead is not an important COPC at the Site.

21) Section 3.1.1.3.1 (Page 23) – Discussion of the comparison of Site and background concentrations is not appropriate in this document. All discussion of background should be removed from this document. This is a global comment.

The BHHRA WP presents a preliminary selection of COPCs based on the current Phase I database; there were no COPCs removed from selection based on background. The discussion of background is presented to help inform the development of the Phase II SAP and the Phase II background study. Clarification will be provided for the use of background in the selection of COPCs and risk characterization sections.

22) Section 3.1.1.4 (Page 35-36) - The data gaps analysis presented is lacking in detail. Please add a discussion of the temporal variability. Because data were collected during one calendar year, additional discussion/evaluation is needed on how these data compare with other years when climatic conditions, groundwater movement, and surface water flow conditions are different. Expand the discussion regarding sample density to include an evaluation of the variability of the data within each EU. If data are highly variable and sample density is low, this would also indicate that additional sampling may be warranted. It should be noted that any future data collected must be considered in the COPC selection. The discussion of surface water and sediment data concluded the sampling density is moderate. However, given that only one year of sampling has been conducted, the temporal representativeness of the data would be improved with additional data collection. There is no discussion of game or fish tissue that may be ingested by recreational receptors who may hunt or fish or that data for these exposure media are lacking. The workplan must discuss the limitations of estimating game/fish tissue concentrations.

As noted above in the response to Comment 15 regarding Section 3.1.1, a discussion of the representativeness of the data for each EU and media type will be added, including discussions of temporal and spatial variability. Some of that discussion will be responsive to this comment as well, and will be referenced or repeated as appropriate.

The BHHRA WP will be revised to discuss how COPCs will be selected for game and fish tissue. The exposure assumptions and intake models/equations for the game and fish ingestion exposure

scenarios will be included in the Table 4 series for the BHHRA as interim deliverables; the interim deliverable will include a cover memo describing the overall approach and details on the methodology; the BHHAR WP will be revised to note the submittal of these tables as interim deliverables.

23) Section 3.1.1.4 (Page 36) - As noted above, chemicals should not be removed during the COPC selection process on the basis of background (USEPA 2002b). Remove any statements that discuss removal of chemicals from the list of COPCs due to background.

The BHHRA WP presents a preliminary selection of COPCs based on the current Phase I database. The discussion of background is presented to help inform the development of the Phase II SAP. Because this is a preliminary selection of COPCs, and as indicated in the BHHRA WP, a final selection of COPCs will be conducted based on the final BHHRA database that will include the data from all phases of site investigation.

24) Section 3.1.2.1 (Page 36) –There appears to be confusion regarding variability and uncertainty. In risk assessment, the central tendency exposure (CTE) and reasonable maximum exposure (RME) are intended to represent the range of *variability* within the population of interest, whereas use of the 95% upper confidence limit (95UCL) on the mean is intended to address *uncertainty* in the exposure point concentration (EPC). RME exposure parameters represent reasonable maximums, such that exposure parameters are adequately conservative for high-end exposures. However, uncertainty in the mean applies to both the CTE and RME scenarios (USEPA 1992; 2001); per USEPA guidance, the 95UCL should be employed as the EPC for both (see Section 1.2.4 of USEPA [2001] for an explicit statement in this regard). Please revise this discussion as appropriate.

The BHHRA Work Plan will be revised to clarify the variability and uncertainty relative to the CTE and RME exposure scenarios, and the use of the 95 percent UCL statistic.

25) Clarification is also needed in discussion of the "UCL". USEPA recommends that the 95UCL <u>of the arithmetic mean</u> for each exposure area be used as the EPC when calculating exposure and risk at that location (USEPA 1992).

The BHHRA Work Plan will be revised to clarify that the 95 percent UCL of the arithmetic mean is used.

26) The maximum concentration should not be selected as the EPC when the 95UCL exceeds the maximum concentration. The approach outlined in the workplan is inconsistent with USEPA's *ProUCL Technical Guide* (Version 5.1; USEPA 2015).

The BHHRA Work Plan will be revised to clarify that the use of the maximum in the 95 percent UCL of the arithmetic mean statistic will follow the ProUCL guidance.

27) Section 3.1.2.2 (Page 37) – Currently, the workplan only includes blank example table templates for the exposure parameters. Revise the workplan to include the actual exposure parameters that are intended for use in the HHRA. This is necessary so that consensus can be reached on selected values when they are based on professional judgement or are considered to be Site-specific.

The RI/FS Work Plan did not require the completion of the Risk Assessment Guidance for Superfund (RAGS) Part D table 4s as part of the BHHRA WP. The completed Table 4 series for exposure assumptions and intake equations will be submitted as an interim deliverable. The interim deliverable will include a cover memo describing the overall approach and details on the methodology; the Work Plan will be revised to note the submittal of these tables as interim deliverables.

28) Section 3.1.2.2 (Page 37) – Please include the following in the list of guidance documents:

- Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Parameters. OSWER Directive 9200.1-120 (EPA 2014)
- Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A) (EPA 1989)
- Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (EPA 2002b)
- Standard Default Exposure Factors. OSWER Directive 9285.6-03 (EPA 1991)

The BHHRA WP will be revised to include the guidance documents noted.

29) Section 3.1.2.2 (Page 37) – It is unclear how the concentrations in air will be estimated for use in risk calculations. Please provide text describing the proposed approach; include specifics on the equation and inputs/assumptions that will be used to calculate the particulate emission factors (PEFs).

The RI/FS Work Plan did not require the completion of the RAGS Part D Table 4 series as part of the BHHRA WP. The exposure assumptions and intake models/equations for this exposure scenario will be included in Table 4s for BHHRA; the completed Table 4 series will be submitted as interim deliverables. The interim deliverable will include a cover memo describing the overall approach and details on the methodology; the Work Plan will be revised to note the submittal of these tables as interim deliverables.

30) Section 3.1.2.2 (Page 37) – Rather than reference the "*USEPA RSL exposure equations*", please include the dose-based equations that will be used to calculate daily intake rates for the various exposure routes that are complete at the Site.

The RI/FS Work Plan did not require the completion of the RAGS Part D table 4 series as part of the BHHRA WP. The exposure assumptions and intake models/equations for this exposure scenario will be included in the Table 4 series for BHHRA; the completed Table 4s will be submitted as interim deliverables. The interim deliverable will include a cover memo describing the overall approach and details on the methodology; the Work Plan will be revised to note the submittal of these tables as interim deliverables.

31) Section 3.1.2.2 (Page 37) – Please include information regarding the age range for receptors at the Site and the approach for time-weighting the exposure of receptors based on their lifetime exposure risks, as recommended in USEPA guidance (USEPA 1989).

The RI/FS Work Plan did not require the completion of the RAGS Part D table 4s as part of the BHHRA WP. The exposure assumptions and intake models/equations for this exposure scenario will be included in the Table 4 series for BHHRA; the completed Table 4 series will be submitted as interim

deliverables. The interim deliverable will include a cover memo describing the overall approach and details on the methodology; and, the Work Plan will be revised to note the submittal of these tables as interim deliverables.

32) Section 3.1.3 (Page 38) – Please include information on the sub-chronic exposure scenarios, if any, that will be evaluated and provide an explanation for how this evaluation will differ from the chronic exposure evaluation.

The RI/FS Work Plan did not require the completion of the RAGS Part D table 4s as part of the BHHRA WP. The exposure assumptions and intake models/equations for this exposure scenario will be included in the Table 4 series for BHHRA; the completed Table 4 series will be submitted as interim deliverables. The interim deliverable will include a cover memo describing the overall approach and details on the methodology; and, the Work Plan will be revised to note the submittal of these tables as interim deliverables.

33) Section 3.1.3 (Page 38) – For metals with different toxicity values for different chemical forms, the toxicity values selected should be based on the chemical form most similar to that expected to occur at the Site. Points to note regarding chemical form are listed below for consideration.

Two oral RfD values are available for cadmium, depending on exposure medium (food or water). The value for water is assumed to apply to surface water and groundwater, while the value for food is assumed to apply to all other media (i.e., soil, sediment, fish and game tissue, and air).

Two oral RfD values are available for manganese depending on exposure medium (diet or non-diet). The value for diet is assumed to apply to items in the diet (i.e., fish and game tissue), while the value for non-diet is assumed to apply to all other media types (i.e., soil, sediment, air, and water). The non-diet RfD for manganese (4.7E-02 mg/kg-day) is based on the oral RfD of 1.4E-01 mg/kg-day in the diet. In accordance with recommendations in IRIS, for application to non-diet exposures, the RfD should be adjusted by dividing by a modifying factor of 3.

The RSL table identifies an oral slope factor for Cr(VI). However, IRIS states "No data were located in the available literature that suggested that Cr(VI) is carcinogenic by the oral route of exposure." For this reason, Cr(VI) should not be evaluated as an oral carcinogen.

Chromium exists in the environment mainly as Cr(III) (ATSDR 2000). However, because the valence state of chromium in soil or water at this Site is not known and data are available only for total chromium, risk calculations should assume the ratio of Cr(III) to Cr(VI) is 6:1 (EPA 2013).

The BHHRA WP will be revised to expand and clarify the basis of toxicity values.

34) Section 3.1.4 (Page 40) – Please provide a table summarizing target organ for each COPC that will be used in the HHRA when evaluating non-cancer hazards.

The RI/FS Work Plan did not require the completion of the RAGS Part D table 5 series as part of the BHHRA WP. The toxicity assessment information including target organs for this exposure scenario will be included in Table 5 series for BHHRA; the completed Table 5 series will be submitted as interim deliverables. The interim deliverable will include a cover memo describing the overall

approach and details on the methodology; and, the Work Plan will be revised to note the submittal of these tables as interim deliverables.

35) Section 3.1.4.1 (Page 40) – Please provide a list of the uncertainties that will be discussed in the HHRA. The following uncertainties are expected to be discussed at a minimum:

Uncertainties in Exposure Assessment:

Uncertainties from exposure pathways not evaluated

Uncertainties from chemicals not evaluated

Uncertainties in exposure point concentrations

Uncertainties in data adequacy (spatial and temporal representativeness of each media type)

Uncertainties in non-detect results - detection limit adequacy

Uncertainties in human exposure parameters

Uncertainties is dietary tissue estimation

Uncertainties in Toxicity Values

Uncertainties in Risk Estimates

The BHHRA WP will be revised to expand and clarify the uncertainties that will be discussed in the BHHRA.

References submitted with comments

USEPA 1989. Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response, Washington, D.C. EPA/540/1-89/002. December.

USEPA 1991. Standard Default Exposure Factors. OSWER Directive 9285.6-03.

USEPA. 1992. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. Supplemental Guidance to RAGS: Calculating the Concentration Term. Publication 9285.7-081.

EPA. 2001. *Risk Assessment Guidance for Superfund: Volume III, Part A, Process for Conducting Probabilistic Risk Assessment.* U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA 540-R-02-002. December 2001.

EPA. 2002a. Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA 540-R-01-003. September. <http://www.epa.gov/oswer/riskassessment/pdf/background.pdf>

USEPA 2002b. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites. OSWER 9355.4-24.

USEPA 2014. OSWER Directive 9200.1-120. Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Parameters.

USEPA. 2015. ProUCL Version 5.1.00 Technical Guide. U.S. Environmental Protection Agency, Office of Research and Development. EPA/600/R-07/041. October 2015. https://www.epa.gov/sites/production/files/2016-05/documents/proucl_5.1_user-guide.pdf.

USEPA. 2017a. OLEM Directive 9285.6-56 "Update to the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters". May.

USEPA. 2017b. OLEM Directive 9200.2-177 "Recommendations for Default Age Range in the IEUBK Model". November.

von Lindern, I., M. Stifelman, L. Stanek, AND C. Bartrem. 2016. Estimating Children's Soil/Dust Ingestion Rates through Retrospective Analyses of Blood Lead Biomonitoring from the Bunker Hill Superfund Site in Idaho. ENVIRONMENTAL HEALTH PERSPECTIVES. National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, NC, 124:1462–1470.